MR INSTRUMENTS INC

Section 2 – 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Contact Person*

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MR Instruments, Inc., Inc.
5610 Rowland Road, Suite 145
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2. *General Information*

Name:	MC 3003G-32R Head Coil
Trade Name:	MC 3003G-32R Head Coil
Common Name:	Head Coil
Classification Name:	Magnetic Resonance Diagnostic Device
Classification:	This device is classified by the Radiology Panel into Class II, (21 CFR 892.1000)

3. *Device Description*

The MC 3003G-32R is a multi-channel receive only RF head coil. It has 32 RF elements that are tuned to ^{1}H at 3T (127.8 MHz). Each element has active and passive blocking networks and integrated preamplifiers. The housing is constructed out of a rigid plastic with an opening for patient viewing and comfort. A head support/base is included.

The predicate device, manufactured for General Electric Company, Milwaukee, WI (USA) by MRI Devices Corp., HRH-127-8 Head Array for GE Signa 3T Excite MRI System (K024352), is also a multi-channel receive only RF head coil. The MC 3003G-R32's fundamental construction and use of materials (as defined above) is similar to the predicate device. (See Attachment B for device drawings.)

4. *Intended Use*

The MR Instruments MC 3003G-32R Head Coil is to be used in conjunction with a Magnetic Resonance Scanner to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.

5. *Substantial Equivalence Comparison*

The MC 3003G-32R Head Coil is substantially equivalent to the following device with respect to intended use and design:

- HRH-127-8 Head Array for GE Signa 3T Excite MRI System (K024352) manufactured for General Electric Company (Milwaukee, WI, USA) by MRI Devices, Waukesha WI, U.S.A.

The similarities between the two devices is that they are both multi-channel receive RF only head coils designed to work with the GE Signa 3.0T Excite MRI System. Both coils are similar in size, shape and construction.

The primary difference between the two devices is that the predicate utilizes an 8 element phased array RF structure as opposed to a 32 element phased array RF structure, which may increase coil sensitivity and may reduce data acquisition time.

6. *Summary of Studies*

Design verification and validation testing was performed to ensure that the coil design specifications and customer requirements were met. Testing activities included electrical bench measurements, electrical/mechanical safety tests, system safety and performance tests with phantoms, predicate device comparison tests and volunteer scans. System tests were conducted using the GE Healthcare Signa 3.0T MR System running standard clinical applications.

7. *Conclusion (statement of equivalence)*

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the MC 3003G-32R Head Coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2008

MR Instruments, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K072931
Trade Name: MR Instruments MC 3003G—32R Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class II
Product Code: MOS
Dated: October 15, 2007
Received: October 16, 2007

Dear Mr. Job:

This letter corrects our substantially equivalent letter of October 30, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MR INSTRUMENTS INC

K072931

Indications for Use Statement

The MR Instruments MC 3003G-32R Head Coil is to be used in conjunction with a GE Signa 3T Excite MR System to produce images and/or spectra of the head, that when interpreted by a trained physician yield information that may assist in diagnosis.

This device is for prescription use.

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072931

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)